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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,788	01/10/2001	Keith Anderson	6116.200-US	8259

7590 05/19/2003

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/19/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/757,788

Applicant(s)

ANDERSON ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following is required under 35 USC 121:

- I. Claims 1-8, drawn to peptides having the amino acid sequence of SEQ ID No:1, is classified in class 530, subclass 300.
- II. Claims 1-8, drawn to peptides having the amino acid sequence of SEQ ID NO: 2, is classified in class 530, subclass 300.
- III. Claims 1-8, drawn to peptides having the amino acid sequence of SEQ ID NO: 3, is classified in class 530, subclass 300.
- IV. Claims 1-8, drawn to peptides having the amino acid sequence of SEQ ID NO: 4, is classified in class 530, subclass 300.
- V. Claims 9-12, drawn to a pulmonary delivery device and method of preparation, is classified in class 514, subclass 2.
- VI. Claim 13, drawn to a method of treatment, is classified in class 514, subclass 866.

This application also contains claims directed to the following patentably distinct species of the claimed invention:

Select **one** from the group of GLP-1 compounds: exendin-3, exendin-4, or Arg34-GLP-1(7-37)-OH.

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Select **one** from the group of spacers: gamma-Glu or beta-Ala.

Select **one** from the group of: Arg34Lys26(N-gamma-glutamyl(N-hexadecanoyl))-GLP-1(7-37)-OH, **or** Arg18, Leu20, Gln34, Lys33 (N-gamma-aminobutyroyl(N-hexadecanoyl)) Exendin-4-(7-45)-NH<sub>2</sub>, **or** Arg33, Leu20, Gln34, Lys18, (N-(gamma-aminobutyroyl(N-hexadecanoyl))Exendin-4(7-45)-NH<sub>2</sub>.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, III, and IV are patentably distinct due to the different structures of each. The polypeptides of groups I, II, III, and IV are composed of amino acids linked by peptide bonds and can assume complex tertiary structures.

The inventions of groups I and V have different modes of operation, different functions and different effects (MPEP 806.04, MPEP 808.01). The invention of group I function is that of a compound. The invention of group V is that of a pulmonary delivery device.

The inventions of groups II and V have different modes of operation, different functions and different effects (MPEP 806.04, MPEP 808.01). The invention of group II function is that of a compound. The invention of group V is that of a pulmonary delivery device.

The inventions of groups III and V have different modes of operation, different functions and different effects (MPEP 806.04, MPEP 808.01). The invention of group III function is that of a compound. The invention of group V is that of a pulmonary delivery device.

The inventions of groups IV and V have different modes of operation, different functions and different effects (MPEP 806.04, MPEP 808.01). The invention of group IV function is that of a compound. The invention of group V is that of a pulmonary delivery device.

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The inventions of group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the compound can be used in the materially different process of affinity purification of antibodies.

The inventions of group II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the compound can be used in the materially different process of affinity purification of antibodies.

The inventions of group III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the compound can be used in the materially different process of affinity purification of antibodies.

The inventions of group IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP 806.05(h)). In the instant case the compound can be used in the materially different process of affinity purification of antibodies.

The inventions of groups V and VI have different modes of operation, different functions and different effects (MPEP 806.04, MPEP 808.01). The invention of group V function is that of a pulmonary delivery device. The invention of group VI function is that of a method of treatment.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

Because the restriction/election requirement is complex, a telephone call to applicant's attorney to request an oral election was not made. See MPEP 812.01.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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1654  
5/16/03

RT

*Brenda Brumback*  
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